K112738

SEP 30 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Medical Co., Ltd.
Address: No.26 HangYu Road, Tianjin Airport Economic Area, TIANJIN
Phone number: 86-22-8761 2426
Fax number: 86-22-6052 6162
Contact: Yi Liu
Date of Application: 9/10/2011

2.0 Device information

Trade name: Andon Health Care Management System Software
Common name: Data management software
Classification name: Data management software

3.0 Classification

Production code: NBW- Blood Glucose Monitoring System.
Regulation number: 862.1345
Classification: II
Panel: Clinical Chemistry

4.0 Predict device information

Manufacturer: Andon Medical Co., Ltd.
Device: Andon Health Care Management System Software
510(k) number: k102678

5.0 Device description

Andon Health Care Management System Software is an optional software accessory for use with AG-608 Single Blood Glucose Monitoring System and AG-608 Multi Blood Glucose Monitoring System, AG-6081 Single Blood Glucose Monitoring System and AG-6081 Multi Blood Glucose Monitoring System, AG-6951Single Blood Glucose Monitoring System and AG-6951 Multi Blood Glucose Monitoring System. When used with the above Blood Glucose Monitoring Systems, Andon Health Care

Management System Software transfers data from the device's memory into a computer for enhanced data management.

6.0 Intended use

Andon Health Care Management System Software is an optional software accessory for use with the Andon blood glucose meters with data management capacities, When used with one of these meters, Andon Health Care Management System Software transfers data from the device's memory into a computer for enhanced data management. Andon Health Care Management System Software is intended for use in home and clinical settings via the internet to assist people with diabetes and their healthcare professionals in uploading, storing, analyzing, and communicating historical blood glucose test results and other biological statistics to support diabetes management. Andon Heath Care System Software is not intended to provide treatment decisions or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

7.0 Summary comparing technological characteristics with predicate device

item	Andon Health Care Management System Software	Andon Health Care Management System Software(K102678)
Indications for use	The ANDON Health Care Management System Software is intended for use in home and clinical settings as an aid for people with users and their health care professionals to review, analyze and evaluate the historical test results to support health management effectively.	The ANDON Health Care Management System Software is intended for use in home and clinical settings as an aid for people with users and their health care professionals to review, analyze and evaluate the historical test results to support health management effectively.
Installation method	Exe file	Exe file
Package Contents	N/A	N/A
Capable of deleting results	Delete all results in meter	Delete all results in meter
Language capabilities	English, Spanish	English, Spanish
Customizable schedule	N/A	N/A
Types of graphs etc.	Coordinates graph	Coordinates graph

Auto-detect COM port	Yes	Yes
System components	PC, USB cable, meter	PC, USB cable, meter
Software platform	Microsoft	Microsoft
Hardware requirements	CPU: optimal at 1,2 GHz+ Main memory: optimal at 256 MB+ RAM Disk space: optimal 200 MB+ free space - at least 100 MB Graphic resolution starting from 1024 x 768, CD-ROM drive, USB interface	CPU: optimal at 1,2 GHz+ Main memory: optimal at 256 MB+ RAM Disk space: optimal 200 MB+ free space - at least 100 MB Graphic resolution starting from 1024 x 768, CD-ROM drive, USB interface
Technology	Visual Basic	Visual Basic
Performance specifications, including any testing	Read memories in meter. Delete all memories in meter Set time to meter Draw table and graph Print Set the personal information	Delete all memories in meter Set time to meter Draw table and graph Print Set the personal information
Meter Compatibility	AG-608 Single Blood Glucose Monitoring System and AG-608 Multi Blood Glucose Monitoring System, AG-6081 Single Blood Glucose Monitoring System and AG-6081 Multi Blood Glucose Monitoring System, AG-6951Single Blood Glucose Monitoring System and AG-6951 Multi Blood Glucose Monitoring System	AG-608 Single Blood Glucose Monitoring System and AG-608 Multi Blood Glucose Monitoring System

8.0 Performance summary

Testing of Andon Health Care Management System Software included system test and unit test.

9.0 Comparison to the predict device and the conclusion

Andon Health Care Management System Software is very similar with the predicted device
Andon Health Care Management System Software(K102678), However, they are intended to use together with 4 additional BGMS: AG-6081 Single Blood Glucose Monitoring System and AG-6081 Multi Blood Glucose Monitoring System, AG-6951Single Blood Glucose Monitoring System and AG-6951 Multi Blood Glucose Monitoring System.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Andon Medical Co., Ltd.
c/o Yi Liu
President
No.26 HangYu Rd., Tianjin Airport Economic Area
Tianjin, 300381
CH - CHINA

SEP 30 2011

Re: k112738
Trade/Device Name: Andon Health Care Management System Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: September 20, 2011
Received: September 20, 2011

Dear: Mr. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K112738

Device Name: Andon Health Care Management System Software

Indication For Use:

Andon Health Care Management System Software is an optional software accessory for use with the Andon blood glucose meters with data management capacities, When used with one of these meters, Andon Health Care Management System Software transfers data from the device's memory into a computer for enhanced data management.

Andon Health Care Management System Software is intended for use in home and clinical settings via the internet to assist people with diabetes and their healthcare professionals in uploading, storing, analyzing, and communicating historical blood glucose test results and other biological statistics to support diabetes management. Andon Heath Care System Software is not intended to provide treatment decisions or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

Prescription Use Yes (21 CFR Part 801 Subpart D) And/Or Over the Counter Use Yes (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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